IN THE CLAIMS:

Applicants, pursuant to 37 C.F.R. § 1.121, submit the following amendments to the claims:

1. (Currently amended) A method for characterising a cell proliferative disorder of the breast tissues of a subject~~; and/or predicting the metastases free survival, and/or predicting the disease free survival, and/or predicting the response of a subject with said disorder to a treatment comprising one or more treatment which target the estrogen receptor pathway or are involved in estrogen metabolism, production or secretion, said method~~ comprising:

a) obtaining a biological sample comprising genomic DNA from a~~the~~ subject having a cell proliferative disorder of the breast tissue;

b) determining, by analyzing the genomic DNA, the methylation status of one or more target CpG dinucleotide sequences ~~positions~~ within the PITX2 gene and/or its regulatory region ~~one or a combination of target nucleic acids, each of said target nucleic acids comprising essentially of all or part of the sequence of a gene taken from the group consisting of TFF1, EGR4, APC, CDKN2A, CSPG2, ERBB2, STMN1, STK11, CA9, PAX6, SFN, S100A2, TGFBR2, TP53, TP73, PLAU, TMEFF2, ESR1, SYK, HSPB1, RASSF1, TES, GRIN2D, PSAT1, CGA, CYP2D6, COX7A2L, ESR2, **PITX2**, VTN, SULT1A1, PCAF, PRKCD, ONECUT2, BCL6, WBP11, (MX1)MX1, APP, ORC4L, NETO1, TBC1D3, GRB7, CDK6, SEQ ID NO: 47, SEQ ID NO: 48, ABCA8, SEQ ID NO: 50, SEQ ID NO: 51, MARK2, ELK1, Q8WUT3, CGB, BSG, BCKDK, SOX8, DAG1, SEMA4B, ESR1 (exon8) and/or their regulatory regions~~ by contacting said one or more target nucleic acid sequences with one or more agents that convert cytosine bases that are unmethylated at the 5'-position thereof to a base that is detectably dissimilar to cytosine in terms of hybridization properties; and

c) determining, based on the methylation status,~~therefrom~~ at least one of: characteristics of the cell proliferative disorder of the subject breast tissue; a prognosis of said subject~~, characteristics of said cell proliferative disorder,~~ ; disease free survival of said subject; and a~~and/or~~

probability of response of said subject to ~~said treatment~~one or more treatment regimens that target the estrogen receptor pathway and/or are involved in estrogen metabolism, production and/or secretion, wherein a method for characterising a cell proliferative disorder of the breast tissues of the subject is afforded.

2. (Currently amended) The method of claim 1, wherein determining in step b) comprises determining the methylation status of one or more target CpG positions within SEQ ID NO:23 or a portion thereof~~one or a combination of target nucleic acids, each of said target nucleic acids comprising essentially of all or part of the sequence of the PITX2 gene a gene taken from the group consisting of TFF1, PITX2 and PLAU is determined~~.

3. (Previously presented) The method of claim 1, further comprising

d) determining a suitable treatment regimen for the subject.

4. (Currently amended) The method of claim 1, wherein determining in c) comprises~~further comprising~~ predicting the response of the[[a]] subject with said disorder to ~~a treatment comprising~~ one or more treatments that~~treatment which~~ target the estrogen receptor pathway or are involved in estrogen metabolism, production or secretion~~ wherein said method is characterised in that the methylation status of one or more CpG positions within at least two target nucleic acid is determined wherein at least one of said target nucleic acids comprises essentially of all or part of the sequence of the gene TFF1 and wherein at least one of said target nucleic acids comprises essentially of all or part of the sequence of the gene PITX2~~.

5. (Currently amended) The method of claim 1, wherein determining in c) comprises~~further comprising~~ characterising a cell proliferative disorder of the breast tissues and/or a metastases thereof; and/or predicting the disease free survival~~wherein said method is characterised in that the methylation status of one or more CpG positions within at least two target nucleic acids is determined wherein at least one of said target nucleic acids comprises essentially of all or part of the sequence of the gene PLAU and wherein at least one of said target nucleic acids comprises essentially of all or part of the sequence of the gene PITX2~~.

6. (Currently amended) The method of claim 1, wherein said one or more~~suitable~~ treatment regimen comprises one or more therapies selected from the group consisting of chemotherapy, radiotherapy, surgery, biological therapy, immunotherapy, antibodies, molecularly targeted drugs, estrogen receptor modulators, estrogen receptor down-regulators, aromatase inhibitors, ovarian ablation, LHRH analogues and other centrally acting drugs influencing estrogen production.

7. (Currently amended) The method of claim 1, wherein said one or more treatment comprises[[is]] an adjuvant treatment~~and said genes are selected from the group consisting of ERBB2, STMN1, TFF1, TMEFF2, ESR1, HSPB1, PITX2, COX7A2L, PLAU, VTN, PCAF, ONECUT2, BCL6, WBP11, TBC1D3, GRB7, CDK6, SEQ ID NO: 47, ABCA8 and SEQ ID NO: 51~~.

8. (Currently amended) The method of claim 2[[1]], wherein said one or more treatment comprises[[is]] an adjuvant treatment~~and said target nucleic acid(s) are selected from the group consisting of SEQ ID NOS: 5, 6, 12, 17, 18, 20, 23, 28, 16, 31, 33, 35, 36, 37, 43, 44, 46, 47, 49 and SEQ ID NO:51~~.

9. (Withdrawn) The method of claim 1, wherein said disorder is a metastatic disease and said genes are selected from the group consisting of APC, CSPG2, ERBB2, STK11, S100A2, TFF1, TGFBR2, TP53, TMEFF2, SYK, HSPB1, RASSF1, PSAT1, CGA, ESR2, ONECUT2, WBP11, CYP2D6, CDK6, ELK1, CGB and DAG1.

10. (Withdrawn) The method of claim 1, wherein said disorder is a metastatic disease and said target nucleic acid(s) are selected from the group consisting of SEQ ID NOS:2, 4, 5, 7, 11, 12, 13, 14, 17, 19, 20, 21, 25, 26, 29, 35, 37, 45, 46, 53, 55 and SEQ ID NO:59.

11. (Currently amended) The method of claim 1, wherein the genomic DNA is obtained from cells or cellular components from ~~which contain DNA, and having~~ a source selected from the group consisting of cell lines, histological slides, paraffin embedded tissues, biopsies, tissue embedded in paraffin or sections thereof, breast tissues, blood, plasma, serum,

lymphatic fluid, lymphatic tissue, duct cells, ductal lavage fluid, nipple aspiration fluid, cerebrospinal fluid, bone marrow and combinations thereof.

12. (Previously presented) The method of claim 1, wherein said cell proliferative disorder of the breast tissue is selected from the group consisting of ductal carcinoma *in situ*, invasive ductal carcinoma, invasive lobular carcinoma, lobular carcinoma *in situ,* comedocarcinoma, inflammatory carcinoma, mucinous carcinoma, scirrhous carcinoma, colloid carcinoma, tubular carcinoma, medullary carcinoma, metaplastic carcinoma, and papillary carcinoma and papillary carcinoma *in situ*, undifferentiated or anaplastic carcinoma and Paget's disease of the breast.

13. (Previously presented) The method of claim 1, wherein said subjects are estrogen and/or progesterone receptor positive.

14. (Currently amended) The method of claim 1, wherein determining in step b) comprises

[[a)]]converting cytosine bases in the genomic DNA sample which are unmethylated at the 5-position, to uracil or another base which is dissimilar to cytosine in terms of base pairing behaviour;

[[b)]]amplifying at least one fragment of the pretreated genomic DNA, wherein said fragments comprise at least 8 base pairs of one or more sequences selected from the group consisting of SEQ ID NOS:250, 251, 372 and SEQ ID NO:373~~SEQ ID NOS: 206 to 449~~ and sequences complementary thereto, and

[[c)]]determining the methylation status of the one or more target genomic CpG dinucleotides by analysis of the amplificate nucleic acids.

15. (Currently amended) The method of claim 14, wherein amplifying at least one fragment comprises use of at least one of methylation sensitive PCR (MSP) and heavy methyl (HeavyMethyl) PCR ~~b) is carried out using one or both of MSP and/or HeavyMethyl~~.

16. (Currently amended) The method of claim 14, wherein determining the methylation status comprises use ~~c) is carried out by means~~ of one or more methods selected~~taken~~ from the

group consisting oligonucleotide hybridisation analysis, methylation-sensitive single nucleotide primer sxtension (Ms-SNuPE)~~Ms SnuPE~~, sequencing, real-time~~Real Time~~ detection probes and oligonucleotide array analysis.

17. (Withdrawn) A nucleic acid molecule consisting essentially of a sequence at least 18 bases in length according to one of the sequences selected from the group consisting of SEQ ID NOS:206-449.

18. (Withdrawn) An oligomer, in particular an oligonucleotide or peptide nucleic acid (PNA)-oligomer, said oligomer consisting essentially of at least one base sequence having a length of at least 10 nucleotides which hybridises to or is identical to one of the nucleic acid sequences according to SEQ ID NOS:206-449.

19. (Withdrawn) A set of at least two oligonucleotides as recited in claim 18.

20. (Withdrawn) A kit comprising a bisulfite, disulfite, or hydrogen sulfite) reagent as well as oligonucleotides and/or PNA-oligomers according to one of the Claims 18 or 19.

21. (Withdrawn) The kit of claim 20, further comprising standard reagents for performing a methylation assay from the group consisting of MS-SNuPE, MSP, Methyl light, Heavy Methyl, nucleic acid sequencing and combinations thereof.

22. (Cancelled)